



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2006-DT-04

October 17, 2005

Mr. Bradley M. Wendzel, President
Coloma Frozen Foods
4145 Coloma Rd.
P.O. Box 520
Coloma, MI 49038

Dear Mr. Wendzel:

The Food and Drug Administration (FDA) has reviewed the labeling of your Nature Blessed Montmorency Tart Cherry Juice Concentrate on your web site at www.colomafrozen.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of this product. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act, 21 USC 321(g)(1)(B)]. The labeling for your product on your web site bears the following claims:

"A natural remedy if you suffer from arthritis, gout, cancer, lupus, fibromyalgia, ... or heart problems."

"Helps relieve Arthritis and Gout pain."

"Tart Cherry Juice has been found to help drastically reduce the pain associated with arthritis and fibromyalgia."

"Tart cherries are an excellent source of compounds with ... anti-inflammatory properties. These compounds ... may help relieve the pain of gout and/or arthritis."

"The same chemicals that give tart cherries their color may relieve pain better than aspirin and ibuprofen."

"How does Tart Cherry Juice help with Arthritis? ... Tart cherry juice has been shown to inhibit both of the enzymes responsible for causing pain Tart cherry juice contains flavonoid compounds that function in the same manner as aspirin, and ibuprofen derivatives and can inhibit

both of the pain causing enzymes, therefore helping to allieve [sic] the pain associated with arthritis.”

“How does Tart Cherry Juice help with Fibromyalgia? The anthocyanins found in tart cherry juice contain high levels of Cox-1 and Cox-2 inhibitors, which function in the same manner as ibuprofen and may help with pain relief for people with fibromyalgia. In addition, Tart cherry juice may play a role in alleviating some of the pain and discomfort brought on by fibromyalgia because the cherries contain significant amounts of melatonin, which help regulate the sleep cycle. Sleep regulation is one key treatment of fibromyalgia.”

“What are the benefits of drinking Tart Cherry Juice concentrate? ... Leading researchers have found that tart cherries have compounds that help relieve the pain of arthritis [and] gout The research also demonstrated that the compounds in tart cherries have shown to be as much as 10 times more effective in fighting joint and muscle inflammation than aspirin. ... Other potential health benefits for tart cherry concentrate include... inhibiting the growth of colon cancer tumors.”

This list of claims is not intended to be all-inclusive, but represents the types of claims found in your product labeling.

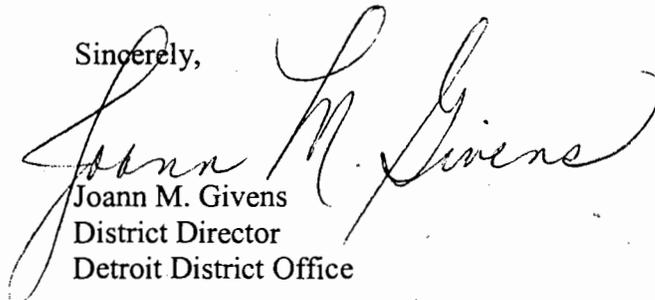
These claims cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act (21 USC 355), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

Failure to promptly correct these violations may result in enforcement action without further notice. Enforcement action may include seizure of violative products, injunction against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Your reply should be directed to Judith A. Putz, Compliance Officer at above address.

Sincerely,



Joann M. Givens
District Director
Detroit District Office